BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTERS OF	)
	)
APPLICATION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER FOR A KIDNEY TRANSPLANT SERVICE	)
	)
Docket No. 17-03-2405	)
	)
and	)
	)
APPLICATION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER FOR A LIVER TRANSPLANT SERVICE	)
	)
Docket No. 17-03-2406	)

MEDSTAR FRANKLIN SQUARE MEDICAL CENTER'S MOTION TO SUBMIT ADDITIONAL DATA AND SET BRIEFING SCHEDULE

MedStar Franklin Square Medical Center ("MFSMC"), through undersigned counsel and pursuant to COMAR §§ 10.24.01.01 and 10.24.01.10(B)(3)(a) and (e), hereby requests the Commission to set a schedule for additional briefing based on the significant changes in transplant data that have occurred since this matter was filed and fully briefed.

By way of background, MFSMC submitted the instant applications on or about August 14, 2017. Final responses to Completeness questions were submitted on or about August 23, 2018. Johns Hopkins Hospital ("JHH") and the University of Maryland Medical Center ("UMMC") submitted their interested party comments on or about October 15, 2018, and MFSMC submitted its responses thereto on or about November 20, 2018. Data submitted by both parties dated from calendar year 2016.

In the context of a field where data evolve constantly and new statistics are presented bi-annually for public review, the data and metrics upon which these applications are to be evaluated have changed significantly in the more than two years since the applications were filed, particularly as they relate to the Project Review Standards in the State Health Plan, COMAR § 10.24.15.04(B). Attached hereto as Exhibit A is a copy of a motion being filed by MedStar Georgetown University Hospital contemporaneously with this one in another pending transplant application by Suburban Hospital for a liver transplant service, Docket No. 17-15-2400. As demonstrated therein, volume data and observed graft survival have changed meaningfully among liver transplant services provided across the Baltimore-Washington region, particularly with regard to the two existing programs in the Living Legacy Foundation OPO. This suggests that the data under review relative to MFSMC's application is no longer relevant.

The State Health Plan mandates that the Commission assess organ transplantation applications as they relate to a host of policies deemed critical to meet the current and future health care system needs of Marylanders and to assure access, quality and cost-efficiency. *See generally* COMAR §10.24.15.02(A) ("Purposes of the State Health Plan"); §10.24.15.03 ("Issues and Policies"). These goals cannot be accomplished with obsolete data. In the context of transplantation data that is updated and reviewed twice yearly by the Scientific Registry for Transplant Recipients (SRTR), this point is of critical relevance.

The regulations controlling the CON application process itself suggest that decisions regarding CON applications are based on relevant and up-to-date data. For example, COMAR §10.24.01.19 provides that any party aggrieved by a decision on a CON application may obtain reconsideration for good cause shown. Good cause is defined to include, *inter alia*, a reconsideration request presenting relevant information not previously presented to the

Commission (and which could not have been presented with reasonable diligence), *see id.* at (B)(1), or a request demonstrating that there have been "significant changes in factors relied upon by the Commission in reaching its decision." *Id.* at (B)(2). MFSMC believes that it has a responsibility to inform the Commission to the need to consider updated information now, so that the parties and the Commission can be confident that its decision is based on the most accurate and contemporary data, factors and circumstances, rather than risking a challenge based on such considerations to a later date.

MFSMC believes that factual changes in data available from recent SRTR reports, illustrate that the MFSMC application cannot fairly be considered on the existing record. Accordingly, MFSMC respectfully requests that the Commission set a schedule for the Interested Parties and MFSMC to update their submissions with current data. Moreover, simultaneous scheduling for review and briefing would seem most appropriate given the elapsed time frame over which the original applications have been under review. MFSMC further suggests that the schedule provide both a time deadline (perhaps 45 days after the relevant Order) and a page limitation (perhaps 25 pages). Again, in light of the request to update data in both MFSMC's applications as well the Suburban application referenced earlier, it seems most efficient to consider conducting the review of all three applications concurrently.

Respectfully submitted,

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November 12, 2019

CERTIFICATE OF SERVICE

I hereby certify that on November 12, 2019, a copy of the foregoing Motion was served by e-mail and first-class mail on:

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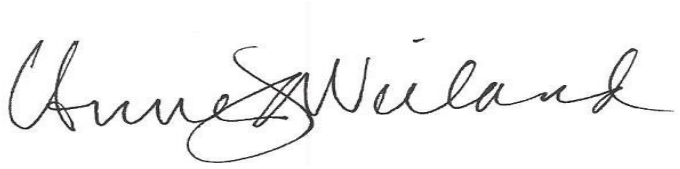
David C. Tobin

I hereby declare and affirm under the penalties of perjury that the facts stated in the foregoing are true and correct to the best of my knowledge, information, and belief.



Anne P. Weiland,
Vice President, MedStar Health
on behalf of MedStar Health
Dated: November 12, 2019

BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF	)
APPLICATION OF SUBURBAN HOSPITAL FOR A LIVER TRANSPLANT SERVICE	)
Docket No. 17-15-2400	)

MEDSTAR GEORGETOWN UNIVERSITY HOSPITAL'S MOTION TO SUBMIT ADDITIONAL DATA AND SET BRIEFING SCHEDULE

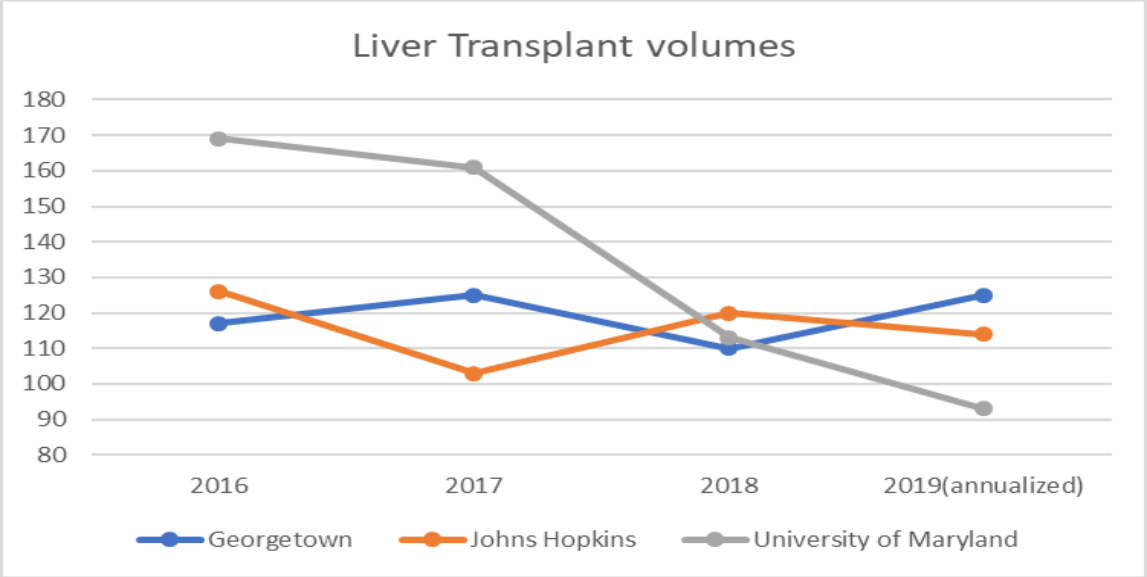
MedStar Georgetown University Hospital ("MGUH"), through undersigned counsel and pursuant to COMAR §§ 10.24.01.01 and 10.24.01.10(B)(3)(a) and (e), hereby requests the Commission to set a schedule for additional briefing based on the significant changes in transplant data that have occurred since this matter was filed and fully briefed.

By way of background, Suburban Hospital ("Suburban") submitted the instant application on or about June 28, 2017. Final responses to Completeness questions were submitted on or about February 18, 2018. MGUH submitted its interested party comments on or about April 30, 2018, and Suburban filed its response thereto on or about May 15, 2018. Data submitted by both parties dated from calendar year 2016. In the Suburban application, data submitted represented the combination of two hospitals' data - Johns Hopkins and University of Maryland – a highly unusual approach since the Scientific Registry for Transplant Recipients (SRTR) requires that individual programs present data individually for review and national comparison.

EXHIBIT A

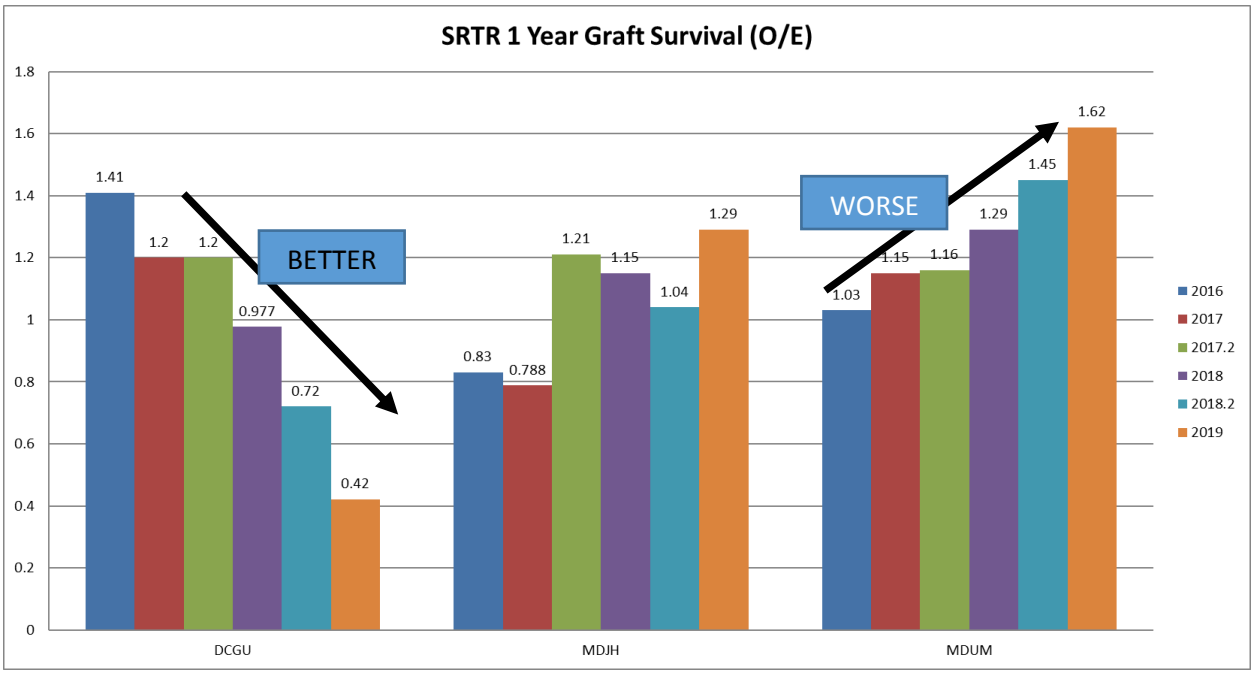
Needless to say, the data and metrics upon which this application are to be evaluated have changed significantly in the 27 months since the application was filed, particularly as they relate to the Project Review Standards in the State Health Plan, COMAR § 10.24.15.04(B).

Underscoring MGUH's point, and with attention to individual programs, more recent data demonstrate that the volume gap between WRTC and LLF liver transplant programs is narrowing, not widening. Volume of both individual programs within LLF have declined, in particular UMMC, the entity that was driving the large volume reported for LLF DSA as shown in the graphic below:



	2016	2017	2018	2019(annualized)
Georgetown	117	125	110	125
Johns Hopkins	126	103	120	114
University of Maryland	169	161	113	93

Liver transplant volumes over time at area centers. Source: https://optn.transplant.hrsa.gov/

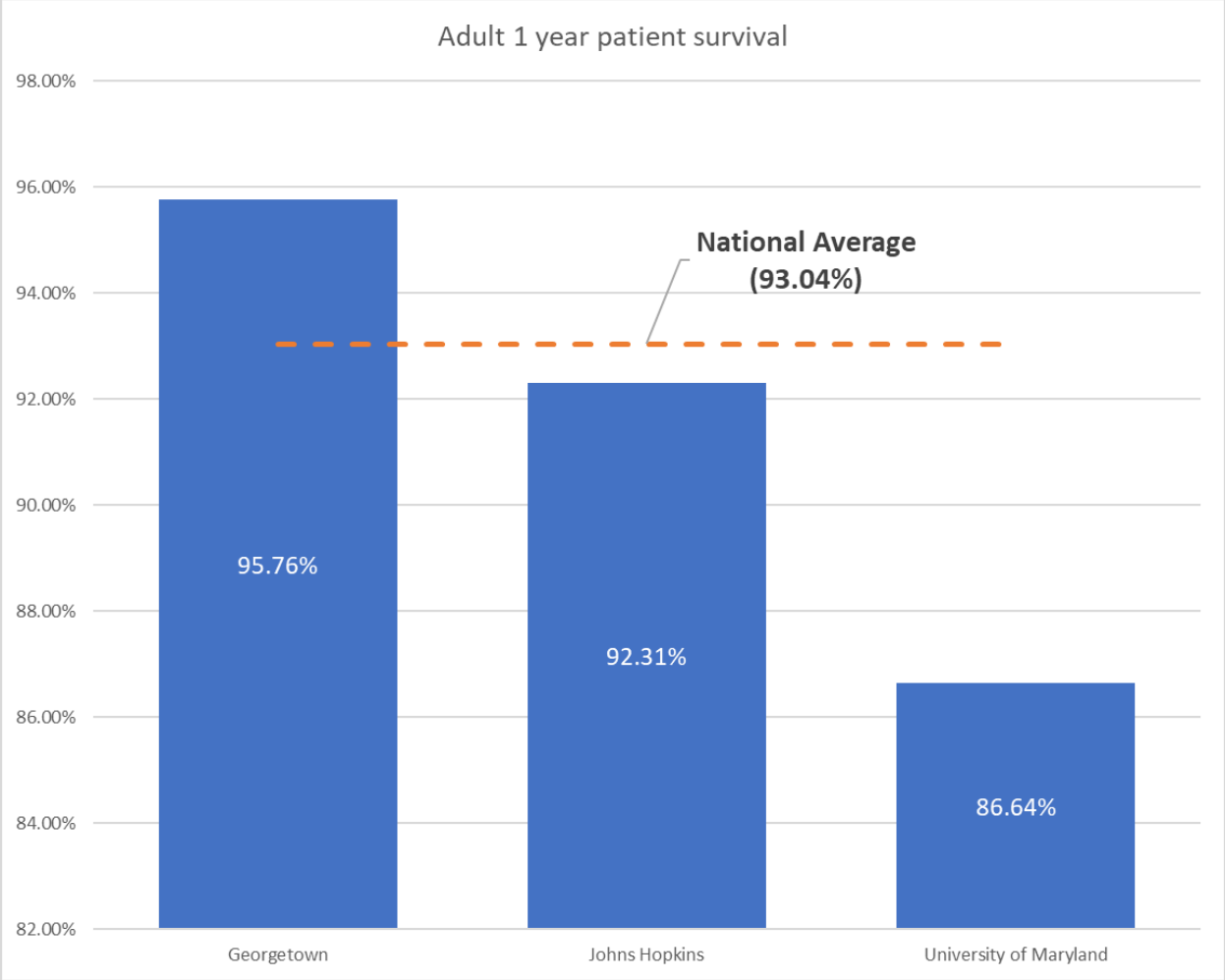


One year post transplant graft survival (observed/expected). Source: https:// srtr.org (accessed 10/9/19).[1]

The relationship between short-term changes in volume and quality outcomes is demonstrated above. Georgetown has maintained transplant volume over time while achieving superior patient outcomes. Overall transplant volume has decreased in Baltimore, a phenomenon that may be seen when programs react to a decline in patient outcomes by taking a more conservative approach to transplant and patient candidacy, i.e. donor and recipient selection. This same trend was seen after JHU experienced poor outcomes and entered into a systems improvement agreement by the Centers for Medicare and Medicaid earlier this decade. Thus, to the extent that a purportedly "widening" volume gap was cited as support for Suburban's application, the most recent data undermine any such argument. Moreover, recent data

[1] The graph above shows the ratio of "observed" to "expected" outcomes over time. The above data reflect this with O/E ratios below 1.0 being better than expected based on patient and donor characteristics and accounting for severity of illness. The Georgetown program has shown a sustained improvement in post-transplant survival. Only six centers in the United States currently have achieved this rating.

demonstrate the increasingly superior outcomes of the MGUH transplant program. MGUH is the only program in the Washington-Baltimore region, indeed only one of six in the nation, with one-year graft and patient survival exceeding national averages: Georgetown's most recent one-year graft and patient survival (July 2019) are 96.09% and 96.06% respectively.



Adult one-year graft and patient survival after liver transplant and national average. Source: https:// srtr.org (accessed 10/9/19).

The point of the foregoing is that the State Health Plan mandates that the Commission assess organ transplantation applications as they relate to a host of policies deemed critical to meet the current and future health care system needs of Marylanders and to assure access, quality

and cost-efficiency. *See generally* COMAR §10.24.15.02(A) ("Purposes of the State Health Plan"); §10.24.15.03 ("Issues and Policies"). These goals cannot be accomplished with obsolete data. In the context of transplantation data that is updated and reviewed twice yearly by SRTR, and followed closely by all in the field, this point is of critical relevance.

As well, the regulations controlling the CON application process itself suggest that decisions regarding CON applications are based on relevant and up-to-date data. For example, COMAR §10.24.01.19 provides that any party aggrieved by a decision on a CON application may obtain reconsideration for good cause shown. Good cause is defined to include, *inter alia,* a reconsideration request presenting relevant information not previously presented to the Commission (and which could not have been presented with reasonable diligence), *see id.* at (B)(1), or a request demonstrating that there have been "significant changes in factors relied upon by the Commission in reaching its decision." *Id.* at (B)(2). MGUH believes that it has a responsibility to alert the Commission to the need to consider updated information now, so that *both* parties, and the Commission, can be confident that its decision is based on the most accurate and contemporary data, factors and circumstances, rather than leaving a challenge based on such considerations to a later date.

MGUH believes that the foregoing examples of most recent data available illustrate that the Suburban application cannot fairly be considered on the existing record based on out-of-date statistics. Accordingly, MGUH respectfully requests that the Commission set a schedule for both Suburban and MGUH to update their submissions with current data. Moreover, simultaneous scheduling for briefing would seem most appropriate given the elapsed time frame over which these original applications have been under review. MGUH further suggests that the schedule provide both a time deadline (perhaps 45 days after the relevant Order) and a page

limitation (perhaps 25 pages). Finally, MedStar Franklin Square Medical Center ("MFSMC") is, contemporaneously with this motion, making a similar request to update data in its pending liver and kidney transplant applications, Docket Nos. 17-03-2405 and 17-03-2406. In light of the request to update data in connection with both the Suburban application and the MFSMC applications, it would seem most efficient to consider conducting the review of all three applications concurrently.

Respectfully submitted,

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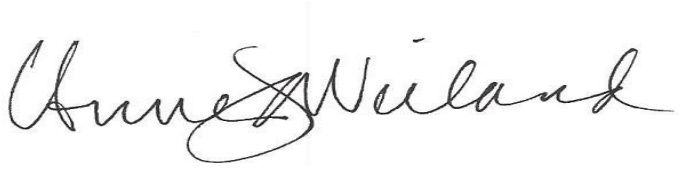
David C. Tobin

I hereby declare and affirm under the penalties of perjury that the facts stated in the foregoing are true and correct to the best of my knowledge, information, and belief.



Anne P. Weiland,
Vice President, MedStar Health
on behalf of MedStar Health
Dated: November 12, 2019